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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,907	06/05/2001	Jon A. Weidanz	49890(48340)	3602
21874	7590	07/26/2005	EXAMINER	
EDWARDS & ANGELL, LLP			SCHWADRON, RONALD B	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1644

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/874,907

Applicant(s)

WEIDANZ ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 81-125 is/are pending in the application.
- 4a) Of the above claim(s) 84, 87-100, 103-123 and 125 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) ~~81-83, 85, 86, 101, 102 and 124~~ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

Art Unit: 1644

1. Applicant's election of Group I and the species IL-2, covalently linked and not containing a carrier in the reply filed on 5/2/2005 and 12/28/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 84,87-100,103-123,125 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/2/2005 and 12/28/2004.

3. Claims 81-83,85,86,101,102,124 are under consideration.

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration (the residence and PO address for Inventor Weidanz). See 37 CFR 1.52(c).

5. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) as follows:

If applicant desires benefit of a previously filed application under 35 U.S.C. 119(e), specific reference to the earlier filed application must be made in the instant application. The first sentence of the specification should be amended to indicate that the instant application claims priority to US provisional application 60/209,536 filed 6/5/2000.

6. Applicant is required to update the status of all US patent applications disclosed in the instant application.

Art Unit: 1644

7. Applicant is required to amend the specification to identify all sequences with the appropriate SEQ. ID. number.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 81-83,85,86,124 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,534,633. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, the single chain antibody portion of the TCR/single chain antibody fusion protein recited in claim 1 is a biologically active polypeptide with a recognition binding site. The claims encompass use of single chain antibodies wherein said antibodies contain Fc regions which would bind to FcR on FcR positive effector cells. The fusion protein would have been prepared in sterile PBS for use in in vitro assays. Claim 2 discloses that the fusion protein contains a single chain alpha beta TCR.

Art Unit: 1644

10. Based on the Example 1 of the specification, the terms "TCR" and "alpha and beta chain TCR" are interpreting as encompassing TCR or TCR chains that contain the relevant variable domains, but do not necessarily contain constant domains or intact constant domains found in the naturally occurring TCR/ TCR alpha or beta chain. Example 1 refers to single chain TCR wherein the disclosed molecule lacks alpha chain constant regions.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 81-83,85,86,101,102,124 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonneville et al. (US Patent 5,723,309).

Bonneville et al. teach soluble heterodimeric TCR fusion proteins wherein a TCR is linked to IL-2 (see column 3, lines 40-52 and column 2, last four paragraphs). Bonneville et al. teach a therapeutic composition containing soluble TCR fusion proteins wherein a TCR is linked to IL-2 (see column 5, lines 52-56). Bonneville et al. teach that the therapeutic composition was administered by injection (see column 5, penultimate paragraph) indicating that it must contain a sterile pharmaceutically acceptable carrier

because the antibody would be present in a pharmaceutically acceptable fluid and drugs for human intravenous use must be sterile. Bonneville et al. teach that the TCR can be a covalently linked single chain TCR containing alpha and beta chain variable regions (see abstract and column 2, penultimate paragraph). Bonneville teach that the soluble TCR can contain V alpha/C delta and V beta/C gamma chains (see column 2, penultimate). When said TCR were linked to the IL-2 protein to make the TCR/IL-2 fusion protein, the C delta and or C gamma portion of the TCR would function as a "peptide linker". Alpha/beta TCR recognize a particular antigen (see column 1, third paragraph). IL-2 is specific for recognition of an effector cells (immune cells expressing IL-2 receptor such as activated T cells).

13. Claims 81-83,85,86 are rejected under 35 U.S.C. 102(b) as being anticipated by Weidanz et al. (WO 99/18129).

Weidanz et al. teach the claimed soluble single chain alpha beta TCR fused to an Ig light chain via a linker (see claims 1,2,4 and page 4, penultimate paragraph). The alpha beta chains of the TCR are covalently linked (see claim 1). The TCR can be specific for a single antigen (see example 1). The aforementioned protein can also contain the tag Factor Xa (see page 30 and claim 14) wherein the Factor Xa would inherently bind leucocytes or platelets which express Factor Xa receptor. The TCR fusion protein of claim 15 contains the tag linked to the TCR with an intervening CK or C $\lambda$  chain wherein said chain would function as a "peptide linker".

14. Claims 81-83,85,86 are rejected under 35 U.S.C. 102(b) as being anticipated by Weidanz et al. (WO 98/39482).

Weidanz et al. teach the claimed soluble single chain alpha beta TCR fused to an Ig light chain via a linker (see claims 1,2,4 and page 4, penultimate paragraph). The alpha beta chains of the TCR are covalently linked (see claim 1). The TCR can be specific for a single antigen (see example 1). The aforementioned protein can also contain the tag Factor Xa (see page 24 and claim 16) wherein the Factor Xa would inherently bind leucocytes or platelets which express Factor Xa receptor. The TCR fusion protein of claim 16 contains the tag linked to the TCR with an intervening CK or C $\lambda$  chain wherein said chain would function as a "peptide linker".

15. Claims 81-83,85,86 are rejected under 35 U.S.C. 102(b) as being anticipated by Banerji et al.

Banerji et al. teach the claimed soluble single chain alpha beta TCR fused to a carrier protein via a peptide tether (wherein the peptide tether is a peptide linker) (see claim 1). The alpha beta chains of the TCR are covalently linked (see claim 1 and abstract). The TCR can be specific for a single antigen (see examples). The carrier protein can be protein A (see page 11) wherein protein A would inherently bind effector cells expressing the appropriate isotype of Ig bound by protein A.

16. Claims 81-83,85,86,124 are rejected under 35 U.S.C. 102(e) as being anticipated by Weidanz et al. (US Patent 6,534,633).

Claims 1-31 of Weidanz et al. teach the claimed fusion protein wherein the single chain antibody portion of the TCR/single chain antibody fusion protein recited in claim 1 is a biologically active polypeptide with a recognition binding site. The claims encompass use of single chain antibodies wherein said antibodies contain Fc regions which would bind to FcR on FcR positive effector cells. Claim 2 discloses that the fusion protein contains a single chain alpha beta TCR. Weidanz et al. teach a composition containing said fusion protein and a sterile pharmaceutically acceptable buffer (see column 41).

17. Claims 81-83,85,86,124 are rejected under 35 U.S.C. 102(a) as being anticipated by Weidanz et al. (WO 00/23087).


Claims 1-28 of Weidanz et al. teach the claimed fusion protein wherein the single chain antibody portion of the TCR/single chain antibody fusion protein recited in claim 1 is a biologically active polypeptide with a recognition binding site. The claims encompass use of single chain antibodies wherein said antibodies contain Fc regions which would bind to FcR on FcR positive effector cells. Claim 2 discloses that the fusion protein contains a single chain alpha beta TCR. Weidanz et al. teach a composition containing said fusion protein and a sterile pharmaceutically acceptable buffer (see page 63).

Art Unit: 1644

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644

  
RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1800-1600